UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

WHITNEY BEAUBIEN, as Personal Representative of the Estate of CRAIG BEAUBIEN,

Plaintiff,

v.

Case No.: 21-11000
Hon. Gershwin A. Drain

CHARU TRIVEDI, M.D., *et al*.,

Defendants.
_____/

OPINION AND ORDER GRANTING DEFENDANT'S RENEWED DAUBERT MOTION TO STRIKE DR. RUSSELL PACHYNSKI'S OPINION ON REDUCED SURVIVAL [ECF No. 81]

I. INTRODUCTION

This is a medical malpractice action alleging that Defendant Charu Trivedi, M.D., breached the standard of care by failing to timely diagnose Plaintiff Whitney Beaubien's husband, Craig Beaubien ("Beaubien"), with terminal renal cell carcinoma ("RCC"). Mr. Beaubien passed away on June 18, 2023. Plaintiff's complaint also alleges a claim against the Toledo Clinic, Inc. d/b/a Toledo Clinic Cancer Centers for medical malpractice. See ECF No. 61.

Defendants previously filed a Daubert Motion to Strike Dr. Russell Pachynski's Opinion Concerning Reduced Survival [ECF No. 69]. The motion urged the Court to strike a supplemental expert report authored by Plaintiff's expert, Dr. Russell Pachynski, M.D., a board-certified oncologist. The Court denied the motion without prejudice and reopened discovery "for the narrow purpose of allowing the parties to depose Dr. Pachynski about his supplemental report." ECF No. 79, PageID.2260. The Court noted that "if additional briefing—beyond what has already been filed—is required, the Court will impose a limit of five pages. . ." ECF No. 79, PageID.2263.

Presently before the Court is Defendants' Renewed Daubert Motion to Strike Dr. Russell Pachynski's Opinion on Reduced Survival. It was filed on May 3, 2024. Plaintiff responded on May 10, 2024, and Defendants replied on May 17, 2024. The Renewed Motion is fully briefed. Upon review of the parties' briefing and applicable authority, the Court concludes oral argument will not aid in the resolution of this matter. Accordingly, the Court will resolve the Plaintiff's Motion to Amend on the briefs. *See* E.D. Mich. L.R. 7.1(f)(2).

For the reasons set forth below, Defendants' Renewed Motion is **GRANTED**.

II. Factual and Procedural Background

On November 27, 2018, Mr. Beaubien began care with Dr. Trivedi for polycythemia after blood tests ordered by his primary care physician revealed Beaubien's hematocrit (HCT)—his red blood cell count—was abnormally high at 53.3. Dr. Trivedi did not take any imaging studies to determine the cause of Beaubien's high HCT. Her impression was that Beaubien's polycythemia was secondary to smoking, dehydration, and sleep apnea. Dr. Trivedi ordered lab work and a test to rule out primary polycythemia. She suggested increased fluids, weight loss, smoking cessation, and continued CPAP usage. Dr. Trivedi planned to order a phlebotomy if Beaubien's HCT was above 50 at the follow up appointment. On December 13, 2018, Dr. Trivedi ordered a phlebotomy because Beaubien's HCT remained above 50. She ordered another phlebotomy in February of 2019.

On June 23, 2019, Beaubien went to Promedica Monroe Regional Hospital with complaints of severe headache lasting a week, slight visual/depth perception disturbance; mild left-sided weakness and nausea without vomiting. A CT scan and MRI revealed an 8.3-centimeter tumor in Beaubien's kidney with metastasis to the brain, and multiple bilateral lung nodules. He was transferred to the University of Michigan Hospital on the same day and underwent a lung biopsy, which confirmed metastatic renal cell carcinoma ("RCC") to the lungs and brain.

On July 11, 2019, Beaubien was seen by oncologist Bruce Redman, D.O., who explained metastatic RCC is not curable, and that treatment would be palliative with the goal of prolonged time and quality of life. Treatment consisted of three modalities: (1) stereotactic radiotherapy to address the brain tumor; (2) targeted chemotherapy to attack the cancer directly; and (3) new immunotherapy treatment intended to trigger the body to mount an immune response to cancer. All of this was followed by surgery to resect the remains of the brain tumor.

Nearly forty months after his diagnosis of metastatic RCC to the brain, kidney and lungs, Beaubien has had no recurrence of brain metastasis, however in June of 2021, he was diagnosed with liver metastasis, which continued to progress despite treatment.

Dr. Pachynski reviewed Beaubien's medical records from Dr. Trivedi, the Monroe Regional Hospital, and the University of Michigan Hospital. He drafted a report that was published on July 25, 2022. In his report, Dr. Pachynski concluded that it is "a virtual certainty that the primary tumor in the kidney was detectable with appropriate imaging[,]" such as ultrasound, CT scan, or an MRI, if done in November of 2018 when Plaintiff first began treating with Dr. Trivedi and the Toledo Clinic. ECF No. 63-2, PageID.1126. In reaching his conclusion, Dr. Pachynski relied on the fact that, in June of 2019, the renal tumor was 8.3

centimeters and had progressed to stage IV with lung and brain metastases. *Id*. He further explained:

> Patients with more advanced disease (*i.e*. more metastatic tumor burden) typically have lived with their cancer for longer periods of time, as cancer – on average – tends to grow in an exponential manner in humans. Thus, it follows that a delay in diagnosis and treatment would result in more advanced disease, and thus lowered overall survival.

Id., PageID.1124. However, Dr. Pachynski could not opine on the size of the kidney tumor in November of 2018 and could not determine when or where it first spread. ECF No. 40-5, PageID.411.

Dr. Pachynski further concluded that it is probable that the brain metastasis developed during the seven months when Beaubien's RCC remained undiagnosed and untreated. ECF No. 63-2, PageID.1125. Relying on peer reviewed studies, Dr. Pachynski concluded that, for patients with brain metastasis at the time of RCC diagnosis, only 50% of them were alive at 12 months compared to the 53% of patients who did not have brain metastasis at the time of diagnosis and were alive 48 months after diagnosis. *Id*. He found that Beaubien could have lived an additional 12 to 36 months if no brain metastasis was present in November of 2018, and an additional 9 to 12 months if the brain metastasis was present at that time. *Id*. As such, Dr. Pachynski opined that "given the totality of the circumstances, more likely than not, the delay in diagnosis and treatment of the

patient's metastatic RCC would have led to a decrease in his overall survival." *Id*. at PageID.1124-1125.

Dr. Pachynski was deposed on August 2, 2022. At his deposition, he testified that it was more probable than not that the brain metastasis was not present in November of 2018. ECF No. 40, PageID.411. He further opined that he could not be certain whether micro metastatic disease was present in November of 2018. *Id*. He said that it was "certainly probable that [Mr. Beaubien] had metastatic disease at that point." *Id*. He indicated that micro metastatic disease is present in many cancer patients, however, the disease is not detectable by imaging. *Id*. at PageID.411-412.

Dr. Pachynski stated that Plaintiff's treatment in 2019 would not have included radiation for the brain tumor if the metastasis had not been present in November of 2018 and Plaintiff's RCC was promptly discovered. *Id*. at PageID.413. However, the systemic treatment (chemotherapy) would have been the same—the targeted cabozantinib followed by the immunotherapies ipilimumab and nivolumab. *Id*. In his original Expert Report and at his deposition, Dr. Pachynski provided two general opinions: (1) with earlier diagnosis Beaubien could have lived an additional 12 to 36 months if the brain metastasis was not present in November 2018; and (2) he could have lived an additional 9 to 12 months if they were present in November 2018.

Beaubien lived with cancer until his death on June 18, 2023, 54 months and 21 days following his initial November 2018 visit with Dr. Trivedi, and 47 months and 24 days after his diagnosis. Following Mr. Beaubien's death, Plaintiff submitted a "Supplemental Report". ECF No. 63-2, PageID.1139. His report relies on relatively new data regarding the median overall survival (OS) for kidney cancer patients who participated in immunotherapies ipilimumab and nivolumab. The report explains that the "immunotherapy [Mr. Beaubien] received for kidney cancer had only been FDA approved the year prior, in April 2018 … Thus, data informing us of expected survival in patients receiving this immunotherapy comparing those with and without brain metastasis is relatively new/recent." ECF No. 63-2, PageID.1139. Based on the data he compiled, he updated Mr. Beaubien's median OS to 47- 56 months without brain metastasis and 33 months with brain metastasis.

Defendants take issue with Dr. Pachynski's supplemental report because it "impermissibly takes the analysis a step further to argue that because Decedent responded well to treatment—he lived 48 months from diagnosis wh[ile] the overall survival for patients with brain metastasis is 33 months—he could have lived an additional two years had treatment started earlier assuming he had the same response to treatment and no brain metastasis." ECF No. 63, PageID.1072. Specifically, Defendants maintain that Dr. Pachynski's calculation of "what he

calls [Mr. Beaubien's] response ratio" "manipul[ates] a generally accepted metric in the oncology community—overall survival—to bolster Plaintiff's claim [that Mr. Beaubien] could have lived longer with earlier diagnosis and treatment." *Id*. Accordingly, Defendants aver that Dr. Pachynski's supplemental report is unreliable and should be excluded under Fed. R. Evid. 702 ("Rule 702").

In light of Defendant's arguments, the Court summarized the report and concluded as follows.

> In his report, Dr. Pachynski stated that, '[i]n the pivotal trial that led to the FDA approval, patients with metastatic kidney cancer without brain metastasis treated with the exact same immunotherapy that Mr. Beaubien received lived a median of 55.7 months (~ 4.6 years). At 6 years, approximately 40% of these patients are still alive.' ECF No. 64-5, PageID.1520. In another study, 'the expected survival with brain metastases treated with the same immunotherapy that Mr. Beaubien received had a median survival of 32.7 months[;]' those 'without brain metastases had a median survival of 47.2 months.' ECF No. 64-5, PageID.1520.
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> Dr. Pachynski opines that, because Mr. Beaubien responded well to the new immunotherapy despite having developed brain metastases, Mr. Beaubien 'would have responded the same had he not developed brain metastases.' ECF No. 68, PageID.1813. He arrives at this hypothesis by applying a "1.45x response ratio" to treatment. *Id*. Dr. Pachynski calculated the response ratio by dividing the number of months Mr. Beaubien survived from the date of his diagnosis (48 months) by the overall survival rate for patients with kidney cancer without brain metastases (33 months). ECF No. 64-5, PageID.1521. He then multiplied that ratio (1.45) by the overall survival rate for kidney cancer patients without brain metastases (52 months). *Id*. The result of this multiplication is a survival rate of 75.4 months, and because Mr. Beaubien survived for 48 months [after diagnosis], Dr.

Pachynski concluded that he would have lived 27 months longer had he been earlier diagnosed.

In discussing the reliability of Dr. Pachynski's method of calculating the response ratio, Plaintiff discusses his qualifications and experience in oncology and treatment renal cell carcinoma. She also cites scientific literature, which notes that 'it is important to use multiple endpoints to assess changes in clinical course that occur as a result of the medical intervention.' ECF No. 68, PageID.1812. While the Court understands that new data has emerged to indicate that patients who used the same immunotherapies as Mr. Beaubien have a different survival rate than those who did not use those immunotherapies, Dr. Pachynski does not assert that any new data calculates the survival rate by using a method similar to his calculations of the response ratio.

While the scientific literature discusses generally recognized endpoints medical practitioners use to assess changes in clinical course that occur as a result of the certain medical interventions, Plaintiff does not cite literature discussing the calculation of anything resembling a 'response ratio.' She does not assert that Dr. Pachynski's method in calculating the response ratio is generally accepted in the scientific community. She does not discuss the rate of error involved in performing these calculations. She does not say that other members of the scientific community have employed similar methods to calculate anything like a 'response ratio' to determine a patient's survival rate based on how he/she would have responded to treatment had it began on an earlier date.

Without more information, the Court is unable to reach a conclusion regarding the reliability of Dr. Pachynski's methods for calculating Mr. Beaubien's 'response ratio.' Plaintiff states that, '[t]o the extent that this Court finds that it needs additional clarification regarding Dr. Pachynski's updated opinion, Plaintiff would voluntarily offer Defendants an opportunity to re-depose Dr. Pachynski on his updated opinion on overall survival. It would be highly prejudicial to Plaintiff if Dr. Pachynski's opinion was stricken without him [having] an opportunity to expand upon it in a deposition.' ECF No. 68, PageID.1814. The Court will reopen

> discovery for the narrow purpose of allowing the parties to depose Dr. Pachynski about his supplemental report.

ECF No. 79, PageID.2257-59.

Pursuant to this Court's Order, Dr. Pachynski was deposed on April 1, 2024, about his supplemental report. The Court will discuss the deposition testimony, the supplemental report, the appliable law, and the analysis below.

III. Fed. R. Evid. 702

Under Rule 702, "a person with 'specialized knowledge' qualified by his or her 'knowledge, skill, experience, training, or education' may give opinion testimony if it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' " *United States v. Johnson*, 488 F.3d 690, 698 (6th Cir. 2007) (quoting Fed. R. Evid. 702). "While a proposed expert witness's qualification to testify 'in the form of an opinion . . . is unquestionably a preliminary factual determination for the trial court . . . it is a determination which must be made upon the evidence of the witness' qualifications." *Kingsley Assoc. Inc. v. Del–Met, Inc.*, 918 F.2d 1277, 1286 (6th Cir.1990) (internal quotation omitted); *see* Fed. R. Evid. 104(a); and Fed. R. Evid. 702.

The burden on a party proffering expert testimony is to "show by a preponderance of proof that the expert whose testimony is being offered is qualified and will testify to scientific knowledge that will assist the trier of fact in

understanding and disposing of relevant issues." *Sigler v. Am. Honda Motor Co*., 532 F.3d 469, 478 (6th Cir. 2008).

Rule 702 governs the reliability of an expert's opinion as well. It states that A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

> a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> b) the testimony is based on sufficient facts or data;
> c) the testimony is the product of reliable principles and methods; and
> d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Where a party challenges the testimony of an expert witness, FRE 702 triggers a court's "gate-keeping role" to determine the admissibility of that testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 597 (1993). "The task for the district court in deciding whether an expert's opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to unsupported speculation." *In re Scrap Metal Antitrust Litig*., 527 F.3d 517 (6th Cir. 2008). District courts enjoy

broad discretion in determining whether to admit or exclude expert testimony. *Tamraz v. Lincoln Elec. Co*., 620 F.3d 665, 672 (6th Cir. 2010).

The Supreme Court in *Daubert* identified several factors that courts may consider in determining whether an expert opinion is reliable. This includes: (1) whether a theory or technique has been tested; (2) whether a theory has been subjected to peer review and publication; (3) whether a method has a high known or potential rate of error and whether there are standards controlling the technique's operation; and (4) whether the theory or technique enjoys a "general acceptance" within the relevant scientific community. *Johnson v. Manitowoc Boom Trucks, Inc*., 484 F.3d 426, 429 (6th Cir. 2007) (citing *Daubert*, 509 U.S. at 579).

IV. Analysis

In his most recent deposition, Dr. Pachynski testified that he had "done math and evaluated what [he] believe[s] the patient's overall response to treatment would have been had [Beaubien] received treatment prior to the diagnosis of brain metastasis[,]" but Dr. Pachynski was not "aware of any peer-reviewed articles that do a similar calculation as to what the patient's response would be were they diagnosed prior to the brain metastasis[.]" ECF No. 81-2, PageID.2311. Dr. Pachynski testified that he "calculated" the "reduction in survival" using estimates that he himself "produced." ECF No. 82-3, PageID.2439. He was asked, "[h]ave

you reviewed any peer-reviewed articles that make similar calculations as to response ratio for treatment?" *Id*. He responded,

> Well, I mean, there are -- there are nomograms, several nomograms, for kidney cancer that are used to predict outcomes. For this type of scenario, there's not enough data with the immunotherapy with and without brain mets where there's a particular nomogram to be able to plug this in and -- and -- and get the answer, so to speak. So just because the ipilimumab and nivolumab were approved in 2018. So produced -- to produce those types of predictive either risk calculators, prognostic calculators, et cetera, what -- and to have peer-reviewed and validated, what you need to do is have a large data with usually hundreds to thousands of patients who have been treated, and then go back and look and then actually validate that with at least a second data set. So, you know, this data is – is new enough so I didn't have those tools available to me.

Id. at PageID.2439-40. The balance of Dr. Pachynski's testimony appears to say, in other words, that there are no peer reviewed articles which make similar calculations as his "response ratio" calculations for reduced survival rate.

For these reasons, Defendants argue that "the fact that the data is newer has no bearing on the reliability of his method. There are recognized methods to determine life expectancy and his is not one of them." ECF No. 81, PageID.2266. Additionally, they point to the portion of Dr. Pachynski's testimony which they believe calls his calculation method a "nomogram." According to an article attached to Defendants' motion, medical nomograms "use biologic and clinical variables, such as tumor grade and patient age, to graphically depict a statistical prognostic model that generates a probability of a

clinical event, such as cancer recurrence or death, for a given individual." ECF No. 81-2, PageID.2346. Variables can also include "tumor size, depth of penetration, lymphovascular invasion, age, and or sex. . . [t]reatment per se should be avoided as a covariate unless there are validated data from a randomized clinical trial." *Id*., at 2347.

Following variable selection, "one must choose a statistical model;" several models are listed in the article. *Id*. After a statistical model is selected, multivariate analyses are performed to determine the association between the covariates and the outcome. *See Id*. Nomograms must be validated by testing the model "on different populations to obtain unbiased estimates of model performance and judging its applicability to these populations. "External validation, preferably in multiple, disparate datasets, is the gold standard and should be obtained whenever possible." *Id*., at 2348.

The problem with Dr. Pachynski's calculation is that Plaintiff does not show that it has been validated as a statistical model. Further, it does not account for any variables other than brain metastasis and Beaubien's response to treatment. Dr. Pachynski compares Beaubien's treatment response to other patients who participated in medical studies, some of them had treatment before metastasis, and some had treatment after metastasis. He bases his conclusion—that Beaubien would have lived an additional 27 months had he been earlier diagnosed—on the

fact that he responded well to treatment, and the survival rate of other patients who had treatments with immunotherapy and with non-immunotherapy. Plaintiff also cites scientific literature that discusses rates of survival for RCC patients with and without metastases. Dr. Pachynski's calculations are distinct from other well-established statistical models discussed in the scientific literature, however, because he calculates a potential survival rate that would have occurred had Beaubien been treated earlier. And Dr. Pachynski's supplemental report does not discuss his consideration of other relevant variables, in addition to surgical treatment, such as tumor grade, patient age, sex, metabolic issues, etc., compared to the patients involved in the studies he cites.

Additionally, Plaintiffs fail show that Dr. Pyschinki's method of calculation of the response ratio and Beaubien's would be survival rate has: (1) been tested and validated, (2) been subjected to peer review and publication, (3) that is does not have has a high potential rate of error, or (4) that the method enjoys a "general acceptance" within the relevant scientific community.

Accordingly, the Court finds that Dr. Pachynski's method for calculating the response ratio is unreliable. And the Court will strike Dr. Pachynski's supplemental opinion on reduced survival, pursuant to Fed. R. Evid. 702.

V. CONCLUSION

For the reasons set forth above, Defendants' Renewed Motion to Strike is **GRANTED**.

SO ORDERED.

Dated: June 10, 2024

/s/Gershwin A. Drain
GERSHWIN A. DRAIN
United States District Judge

CERTIFICATE OF SERVICE

Copies of this Order were served upon attorneys of record on June 10, 2024, by electronic and/or ordinary mail.
/s/ Marlena Williams
Case Manager